Audit Report

COLLECTION AND REPORTING OF PATIENT SAFETY DATA WITHIN THE MILITARY HEALTH SYSTEM

Report No. D-2001-037 January 29, 2001

Office of the Inspector General
Department of Defense

Form SF298 Citation Data

Report Date *("DD MON YYYY")* 29Jan2001	**Report Type** N/A	**Dates Covered (from... to)** *("DD MON YYYY")*

Title and Subtitle Collection and Reporting Patient Safety Data Within the Military Health System	**Contract or Grant Number**
	Program Element Number
Authors	**Project Number**
	Task Number
	Work Unit Number
Performing Organization Name(s) and Address(es) OAIG-AUD (ATTN: AFTS Audit Suggestions) Inspector General, Department of Defense 400 Army Navy Drive (Room 801) Arlington, VA 22202-2884	**Performing Organization Number(s)** D-2001-037
Sponsoring/Monitoring Agency Name(s) and Address(es)	**Monitoring Agency Acronym**
	Monitoring Agency Report Number(s)

Distribution/Availability Statement
Approved for public release, distribution unlimited

Supplementary Notes

Abstract
On November 29, 1999, the Institute of Medicine released a report entitled inTo Err is Human, Building a Safer Health System.le The report estimated that as many as 44,000 to 98,000 patients die each year in the United States as a result of medical errors. As a result of the findings in the report, the President issued a memorandum on December 7, 1999, directing the Quality Interagency Coordination Task Force to evaluate the report recommendations. The Assistant Secretary of Defense (Health Affairs) has proposed a centralized, DoD-wide patient safety reporting program to reduce occurrence of medical errors. The program focuses on prevention of medical errors through centralized reporting of patient safety data and sharing the data and lessons learned throughout DoD. The Assistant Secretary of Defense (Health Affairs) requested that we review the proposed patient safety reporting program.

Subject Terms

Document Classification unclassified	**Classification of SF298** unclassified

Classification of Abstract unclassified	**Limitation of Abstract** unlimited
Number of Pages 25	

Additional Copies

To obtain additional copies of this audit report, visit the Inspector General, DoD, Home Page at www.dodig.osd.mil or contact the Secondary Reports Distribution Unit of the Audit Followup and Technical Support Directorate at (703) 604-8937 (DSN 664-8937) or fax (703) 604-8932.

Suggestions for Future Audits

To suggest ideas for or to request future audits, contact the Audit Followup and Technical Support Directorate at (703) 604-8940 (DSN 664-8940) or fax (703) 604-8932. Ideas and requests can also be mailed to:

OAIG-AUD (ATTN: AFTS Audit Suggestions)
Inspector General, Department of Defense
400 Army Navy Drive (Room 801)
Arlington, VA 22202-4704

Defense Hotline

To report fraud, waste, or abuse, contact the Defense Hotline by calling (800) 424-9098; by sending an electronic message to Hotline@dodig.osd.mil; or by writing to the Defense Hotline, The Pentagon, Washington, DC 20301-1900. The identity of each writer and caller is fully protected.

Acronyms

AFIP	Armed Forces Institute of Pathology
IOM	Institute of Medicine
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MHS	Military Health System
MTF	Military Treatment Facility
OASD(HA)	Office of the Assistant Secretary of Defense (Health Affairs)
QuIC	Quality Interagency Coordination Task Force
VA	Department of Veterans Affairs

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

January 29, 2001

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Audit Report on Collection and Reporting of Patient Safety Data Within the Military Health System (Report No. D-2001-037)

We are providing this report for information and use. We conducted the audit in response to your request. We considered management comments on a draft of this report in preparing the final report.

Comments on the draft of this report conformed to the requirements of DoD Directive 7650.3 and left no unresolved issues. Therefore, no additional comments are required.

We appreciate the courtesies extended to the audit staff. Questions on the audit should be directed to Mr. Michael A. Joseph at (757) 766-9108 (mjoseph@dodig.osd.mil) or Mr. Sanford W. Tomlin at (757) 766-3265 (stomlin@dodig.osd.mil). See Appendix B for the report distribution. The audit team members are listed inside the back cover.

David K. Steensma

David K. Steensma
Deputy Assistant Inspector General
for Auditing

Office of the Inspector General, DoD

Report No. D-2001-037 **January 29, 2001**
(Project No. D2000LF-0195)

Collection and Reporting of Patient Safety Data Within the Military Health System

Executive Summary

Introduction. On November 29, 1999, the Institute of Medicine released a report entitled "To Err is Human, Building a Safer Health System." The report estimated that as many as 44,000 to 98,000 patients die each year in the United States as a result of medical errors. As a result of the findings in the report, the President issued a memorandum on December 7, 1999, directing the Quality Interagency Coordination Task Force to evaluate the report recommendations.

The Assistant Secretary of Defense (Health Affairs) has proposed a centralized, DoD-wide patient safety reporting program to reduce occurrence of medical errors. The program focuses on prevention of medical errors through centralized reporting of patient safety data and sharing the data and lessons learned throughout DoD. The Assistant Secretary of Defense (Health Affairs) requested that we review the proposed patient safety reporting program.

Objectives. Our objective was to evaluate the collection and reporting of quality assurance data within the Military Health System with a focus on the management of events potentially affecting patient safety. We did not evaluate the management controls program because the patient safety reporting program is still in the development phase.

Results. Significant effort to collect and report patient safety data is ongoing at the Military Treatment Facility level within the Military Health System. The DoD proposed patient safety reporting program has the potential to improve data consistency and provide a means for sharing the data and lessons learned throughout DoD. To effectively and efficiently implement the proposed patient safety reporting program, an implementation strategy is needed. Without an implementation strategy, the proposed program's potential for improving health care through reduction of medical errors may not be maximized. See the Finding section for a discussion of the audit results.

Summary of Recommendations. We recommend the Assistant Secretary of Defense (Health Affairs) develop an implementation strategy for the proposed patient safety reporting program. The implementation strategy should include goals and performance measures, outline a phased approach for reporting adverse events, identify full-time core staffing, require that patient safety personnel successfully complete program training, and use the Department of Veterans Affairs patient safety database software.

Management Comments. The Acting Assistant Secretary of Defense (Health Affairs) concurred with the finding and recommendations, stating that an implementation strategy is essential and one will be developed to include our specific recommendations. The strategy will include specific goals and performance measures. The burden of data

management will be minimized through streamlined reporting procedures for the low severity adverse events and use of quarterly aggregated reviews for adverse drug events and falls. A management analysis to determine core staffing requirements will be requested. The draft DoD instruction on the Patient Safety Program was revised to include a requirement for patient safety personnel to attend training before participating in the program. The Department of Veterans Affairs patient safety database software is expected to be used beginning in the spring 2001 at the start of the next phase of the program. See the Finding section for a discussion of management comments and the Management Comments section for the complete text of the comments.

Audit Response. The Acting Assistant Secretary of Defense (Health Affairs) comments were fully responsive and no additional comments are required. Actions planned to minimize the burden of data management satisfy the intent of the recommendation to implement a phased approach for reporting adverse events. Based on management comments, we deleted the portion of the recommendation to use Department of Veterans Affairs software during the DoD program pilot phase. Throughout the audit we worked closely with the staff in the Office of the Secretary of Defense (Health Affairs), and we commend the staff on their aggressive approach to implementing corrective actions.

Table of Contents

Background

Quality Interagency Coordination Task Force. On March 12, 1998, the Advisory Commission on Consumer Protection and Quality in the Health Care Industry issued a report to the President entitled, "Quality First: Better Health Care for all Americans." The report recommends establishing two complementary entities—one public and one private—to provide ongoing national leadership in health care quality improvement.

In response to the recommendation regarding the public entity, the President issued a memorandum on March 13, 1998, which directed the Secretary of Health and Human Services to establish the Quality Interagency Coordination Task Force (QuIC). The President directed the QuIC to ensure better coordination among executive agencies with jurisdiction over health programs.

The QuIC is cochaired by the Secretary of Health and Human Services and the Secretary of Labor. The Administrator of the Agency for Healthcare Research and Quality in the Department of Health and Human Services serves as chairman for day-to-day operations. In addition to the Department of Health and Human Services and the Department of Labor, Federal members of the QuIC are the:

- Department of Commerce,
- Department of Defense,
- Department of Veterans Affairs,
- Office of Management and Budget,
- Office of Personnel Management,
- U.S. Coast Guard,
- Federal Bureau of Prisons,
- Federal Trade Commission, and
- National Highway Traffic Safety Administration.

Institute of Medicine Report. On November 29, 1999, the Institute of Medicine (IOM)* released a report, "To Err is Human, Building a Safer Health System." The report estimated that as many as 44,000 to 98,000 patients in the United States die each year from medical errors. The IOM calculated the estimate by extrapolating the results from two separate studies on patient hospitalizations. One was a 1992 study that reviewed hospitalizations in Colorado and Utah, and the other study reviewed patient admissions from a 1984 New York hospital admissions database. The July 5, 2000, issue of the Journal of the American Medical Association contained two reviews of the IOM

*The IOM is an organization that is part of the National Academies. The Federal Government created the National Academies to be advisors on scientific and technological matters. The National Academies are private, non-governmental organizations and do not receive direct Federal appropriations for their work. Studies undertaken for the Government by the National Academies usually are funded by appropriations made available to Federal agencies.

report. One review stated the report exaggerated the number of medical errors and the other review stated the report underestimated the number of medical errors.

The IOM report provides a strategy for addressing errors that occur in the health system and recommends establishing a national goal to reduce the number of medical errors by 50 percent during the next 5 years. The report outlines a four-tiered approach to reduce medical errors with actions to:

- establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety;
- identify and learn from medical errors through both mandatory and voluntary reporting systems;
- raise standards and expectations for improvements in safety through the action of oversight organizations, group purchasers, and professional groups; and
- implement safe practices at the delivery level.

Executive Memorandum. On December 7, 1999, the President directed the QuIC to evaluate the recommendations in the IOM report and provide specific actions that will improve health care outcomes and to prevent medical errors.

QuIC Report to the President. The QuIC issued "Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact" in February 2000. The QuIC agreed with the IOM recommendations and provided the actions that QuIC member agencies will take to address the IOM recommendations.

The QuIC report explained that DoD would implement a confidential patient safety reporting system, modeled after a Department of Veterans Affairs (VA) system, in its hospitals and clinics. The proposed reporting system will collect information on adverse events, medication errors, close calls, and other patient safety issues. The intent of the reporting system is to provide health care professionals and facilities with the information necessary to protect patient safety.

Other DoD-Wide Patient Safety Initiatives. There are many DoD-wide initiatives that have potential for improving patient safety. For example, DoD is developing a new computerized patient medical record that will include an automated entry order system for pharmaceuticals. The computerized record is being developed to assure that all relevant clinical information on a patient is complete, accurate, and available when and where it is needed. DoD also plans to deploy a pharmacy bar-code system that will scan a patient's military identification card and the medication bar code at the time the medication is delivered. The bar-code system will help ensure that a patient is not given medication intended for someone else and reduce the risk of medication errors. We did not review these initiatives, rather we reviewed the collection and reporting of patient safety data.

Objectives

Our objective was to evaluate the collection and reporting of quality assurance data within the Military Health System (MHS) with a focus on the management of events potentially affecting patient safety. We did not evaluate the management control program because the patient safety reporting program is still in the development phase. See Appendix A for a discussion of the audit scope and methodology and for a summary of prior coverage.

Implementing Strategy for Collection and Reporting of Patient Safety Data

Significant effort to collect and report patient safety data is ongoing at the Military Treatment Facility (MTF) level within the MHS. The DoD proposed a patient safety reporting program that has the potential to improve data consistency and provide a means for sharing the data and lessons learned throughout DoD. However, to effectively and efficiently implement the proposed patient safety reporting program, the Office of Assistant Secretary of Defense (Health Affairs) (OASD[HA]) must develop an implementation strategy. The implementation strategy should, at a minimum, identify program goals and performance measures, phase in adverse event reporting, include core staffing, require mandatory training, and include provisions for utilizing VA patient safety database software. Without an implementation strategy that addresses the preceding issues, the potential for improving health care through the reduction of medical errors may not be maximized.

Patient Safety

Patient Safety Data. Patient safety data refers to any information collected on an adverse event. Adverse events are occurrences or conditions associated with care or services that cause or could cause unexpected harm to the patient while providing care or services. Adverse events may be acts of either commission or omission.

Sentinel events constitute a subcategory of adverse events. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) defines a sentinel event as an unexpected occurrence that involves death, serious physical or psychological injury, or risk thereof. The JCAHO identifies the following as sentinel events and may be subject to JCAHO review as a part of the MTF accreditation process:

- an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition; or
- suicide of a patient in a setting where the patient receives around-the-clock care, infant abduction or discharge to the wrong family, rape, hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities, or surgery on the wrong patient or wrong body part.

Although JCAHO requires that the above events be considered sentinel events, reporting of sentinel events to JCAHO is voluntary. During FY 1999, DoD reported 21 sentinel events to JCAHO.

Root Cause Analysis. To determine the circumstances surrounding a potential sentinel event, medical facilities perform a root cause analysis. JCAHO has issued specific criteria for performing root cause analyses. A root cause analysis is a process for identifying the basic or contributing causal factors associated with adverse events. The analysis is conducted by an interdisciplinary team of administration and health care professionals with the required experience and focuses primarily on systems and processes rather than individual performance. The product of the analysis is an action plan that identifies and implements strategies to reduce risk of similar events occurring in the future. The action plan should address responsibility for implementation, oversight, time lines, and strategies for measuring the effectiveness of the actions. Root cause analyses are performed for many serious adverse events that, after research, do not meet the sentinel event criteria.

Significant MTF Effort for Collecting and Reporting Patient Safety Data

Significant effort to collect and report patient safety data is ongoing at the MTF level within the MHS. The six MTFs visited had established programs based on Military Department guidance, and had staffs fully dedicated to the patient safety effort. Additionally, OASD(HA) required the MTFs to report sentinel events to JCAHO, and is in the process of implementing a DoD-wide patient safety reporting program.

Military Department Guidance. Each of the Military Departments has issued guidance requiring the MTFs to establish quality improvement programs. Guidance includes Army Regulation 40-68, "Quality Assurance Administration," December 20, 1989; Naval Bureau of Medicine and Surgery Instruction 6010.13, "Quality Assurance Program," August 19, 1991; and Air Force Instruction 44-119, "Clinical Performance Improvement," August 1, 2000. The primary purpose of these programs is to improve patient safety by delivering quality patient care and reducing the risk of adverse events.

Patient Safety Effort at MTFs. The six MTFs we visited have quality improvement programs for patient safety based on the Military Department guidance and staffs fully dedicated to quality improvement programs. Each quality improvement program provides for ongoing identification and investigation of incidents involving accidents or injuries that adversely affect patients, visitors, or staff. Additionally, the programs investigate deviations from standards of health care. However, collection of patient safety data remains at the MTF. In addition to adverse event reports, the MTFs obtained patient safety information from medical diagnosis reviews, patient chart reviews, and peer reviews.

Each of the six MTFs performed trend analyses on the patient safety information gathered. The results of the analyses were reported to committees within the MTF established to monitor the patient safety efforts and ensure action to reduce adverse events and improve patient safety was taken. MTF adverse event report documentation and committee minutes reflect that the patient safety analyses

have resulted in changes and improvements in systems and processes that improved patient safety. Some examples of procedural changes and process improvements at the MTF include:

- restricting distribution of potentially lethal medications to only premixed doses,
- changing packages of medications that appeared similar,
- decreasing the time it takes to transport seriously ill patients to other medical facilities,
- improving timeliness of scheduling patients for ancillary services, and
- calling patients the day after an outpatient procedure.

Reporting Sentinel Events to JCAHO. In a memorandum dated September 24, 1999, the ASD(HA) requires MTFs to report sentinel events to JCAHO. The JCAHO requires accredited hospitals to review sentinel events; however, reporting sentinel events to JCAHO is voluntary. DoDs mandatory reporting requirement exceeds JCAHO criteria.

When sentinel events are reported to JCAHO, the health care organization is expected to prepare and submit to JCAHO a thorough and credible root cause analysis and action plan within either 45 calendar days of the event or learning of the event. Once the analysis is received, JCAHO will determine if the analysis and action plan are acceptable. During 1999, the 6 MTFs visited had a total of 30 events for which a root cause analysis was performed. Of the 30 events that lead to root cause analyses, the MTFs determined that 4 were sentinel events and reported them to JCAHO. JCAHO found that the submitted root cause analyses and action plans were acceptable.

Centralized Patient Safety Reporting Program. OASD(HA) proposed a centralized DoD-wide program for collecting and reporting patient safety data in the MHS. The DoD instruction, in draft as of January 2001, will require every MTF to establish a dedicated program for avoiding medical mistakes and improving patient safety by focusing on improved medical systems and processes. The cornerstone of the program is the centralized collection and analysis of patient safety data, with emphasis on a nonpunitive philosophy toward those reporting adverse events. Previous studies of adverse event reporting found most adverse events were not reported and the variation of adverse events between medical facilities or within medical facilities over time, may be the result of increased or decreased reporting rather than a change in the number of adverse events. We believe implementation of a centralized patient safety system that advocates one DoD policy with a nonpunitive philosophy has the potential to improve data consistency and provide a means for sharing the data and lessons learned throughout DoD.

Program Implementation Strategy

Although the proposed patient safety reporting program is a valuable tool, its effectiveness could be improved by developing an overall strategy for implementing the program. Such a strategy should include program goals and performance measures for determining the status and success of the patient safety reporting program. The strategy should also include a phased approach for reporting adverse events, core staffing requirements, mandatory training requirements, and provisions for using the VA patient safety database software. Without an implementation strategy that addresses the preceding issues, the potential for improving health care through the reduction of medical errors may not be maximized.

Goals and Performance Measures. Program goals and performance measures have not been developed for the patient safety reporting program. The Government Performance and Results Act of 1993 (the Act) states that Federal managers are disadvantaged in their efforts to improve program efficiency and effectiveness because program goals are not sufficiently identified and adequate program performance data are not available. Although directed toward the overall performance of each agency, the Act does provide a method to improve the management, and ultimately success, of smaller programs. The method consists of:

- establishing performance goals that define the level of performance to be achieved;
- expressing each goal in an objective, quantifiable, and measurable form;
- describing the operational processes and resources required to meet the performance goals;
- providing a basis upon which actual program results can be compared against established performance goals; and
- describing the means to verify and validate measured values.

Significant assets and effort will be required to implement the patient safety reporting program throughout DoD. Personnel and automation resources are needed to establish the reporting system. Personnel at the MTF level will need training on the new program. In addition, health care providers will increasingly be involved with root cause analyses. Establishing performance goals, determining how the goals will be measured, and identifying when actual performance will be compared with the goals will provide a systematic method to optimize benefits.

Phased Approach for Reporting Adverse Event Data. The draft DoD instruction on the patient safety reporting program requires reporting all adverse events and could result in too much information to manage effectively.

OASD(HA) and Armed Forces Institute of Pathology (AFIP) senior managers were not aware of the number of adverse events reports, excluding sentinel events, prepared at the MTFs each year.

Adverse event data from the three medical centers and three community hospitals we visited during the audit are presented in the table below. We believe the variation in the number of adverse events between similar sized MTFs is due to inconsistent reporting and should not be used as the basis for comparing health care quality between MTFs. We did not perform a statistical sample and therefore cannot project the total number of adverse event reports prepared annually by all inpatient MTFs. However, because the 6 MTFs visited had a combined total of 5,792 adverse events, we believe the total for all 89 MTFs in DoD will be a substantial number.

1999 Adverse Events at Audit Sites

Type of MTF	Root Cause Analyses (Sentinel and Other)	Total Adverse Events
Medical Center 1	7	3,071
Medical Center 2	0	282
Medical Center 3	16	1,241
Community Hospital 1	0	141
Community Hospital 2	1	144
Community Hospital 3	6	913
Total	**30**	**5,792**

OASD(HA) senior management was not aware of the volume of MTF adverse events and expressed to us their concerns that the reporting of all adverse events in the initial stages of the proposed patient safety reporting program might result in an overload of data without any focus.

The draft DoD instruction on the patient safety reporting program assigns responsibility for developing and maintaining the database to the AFIP. AFIP senior management was also unaware of the volume of adverse events. AFIP management was especially concerned about the additional staffing and funding required to review, analyze, and trend a large database.

OASD(HA) and AFIP senior managers realize the proposed program will require a significant reporting effort at the MTF level and stress the importance of giving MTFs timely, accurate, and meaningful feedback to ensure program support at the MTFs. To keep the database and workload manageable as well as provide prompt feedback, the program could initially require reporting of only those events that result in a root cause analysis. Such a requirement would help

ensure that the initial focus of the program is on the high-risk areas. Reporting of all other adverse events could be phased in to the program. Senior management agreed.

Dedicated Full-Time Core Staff. OASD(HA) has not adequately staffed the patient safety reporting program to ensure implementation. In response to the December 7, 1999, Presidential memorandum that directs Federal agencies to improve patient safety, OASD(HA) established the DoD Patient Safety Working Group (Working Group). The Working Group meets about every third week and comprises representatives from the Military Department Surgeons General, the Uniformed Services University of Health Sciences, the AFIP, the OASD(HA), and the TRICARE Management Office. The Working Group has the broad tasking to review patient safety issues, identify patient safety initiatives, prepare a patient safety instruction that creates a confidential reporting program, and manage implementation of the program to include training. Despite the magnitude and significance of the Working Group's tasking, none of the members was assigned to the group full time. Each member was assigned to the Working Group as a collateral duty, requiring a substantial amount of effort above and beyond the time needed for the members' primary duties. In addition, military personnel who fill many of the key program management positions are subject to rotate to other positions.

Because DoD is adopting the VA patient safety reporting program, we contacted the VA to determine the size of the core staffing and methodology the VA is using to implement the program. To implement its patient safety reporting program, the VA created the National Center for Patient Safety with 24 full-time personnel positions. The large full-time staff is needed because the National Center for Patient Safety is responsible for issuing patient safety reporting program guidance, conducting associated training courses, and dealing with the program's day-to-day implementation problems. The National Center for Patient Safety will also perform on-site reviews to determine the status of program implementation, along with maintaining and reviewing the patient safety database to identify trends.

We realize that DoD has 89 inpatient facilities and the VA has 173, and the staffing required to implement each patient safety reporting program will vary. Because DoD adopted the VA safety reporting program, a large full-time staff was not required during the early stages of the program's development. However, now that DoD is moving into the program training and implementation phase, some level of full-time core staff is needed for the program to be successful.

Training. To improve the consistency of MTF adverse event reporting, the Working Group is developing a training course for the proposed patient safety reporting program. However, there is no requirement for personnel from the MTFs to participate in the training prior to implementing the program.

Without a centralized patient safety reporting program, MTFs developed inconsistent methods of collecting and tracking adverse event reports. Four of the MTFs visited had patient safety departments that centrally reviewed adverse event reports that could quickly provide detailed information on the types and quantities of adverse events. The two other MTFs relied on individual

departments to review adverse events and to obtain totals. Other than sentinel events, none of the MTFs reported adverse events outside the MTF. Differing collection methods could contribute to the variation in reported adverse events as shown in the preceding table. An extensive review conducted by medical professionals would be required to determine the reason for the variation and is beyond the scope of this audit.

To ensure consistency in the methods for identifying and researching adverse events, the VA developed a 3-day patient safety training seminar and requires hospitals, prior to participating in the patient safety reporting program, to send patient safety personnel to the seminar. The training seminar focuses on establishing a consistent method for identifying, classifying, and reporting adverse events. The seminar outlines a 22-step methodology, along with a standardized form for performing a root cause analysis, and requires attendees to complete numerous case studies on reviewing and reporting adverse events. During FY 2000, the VA offered 8 training seminars at various locations and more than 880 personnel attended the training seminars. Personnel selected for attending were the directors of VA hospital patient safety reporting programs and other key personnel who would most likely be responsible for acting as a root cause analysis team advisor.

OASD(HA) plans for the National Capital Region to be the test pilot site for the proposed patient safety reporting program and has developed a training seminar that parallels the VA seminar. Although the first training seminar was planned for September 2000, readiness training requirements and JCAHO accreditation reviews caused the seminar to slip to October 2000.

We applaud the OASD(HA) decision to pattern the DoD patient safety reporting program training after the VA training. However, we believe OASD(HA) should include a requirement in the implementation strategy for all MTFs to send patient safety personnel to program training prior to participation in the proposed patient safety reporting program. Requiring MTFs to send personnel to patient safety training would help ensure consistency in the centralized database and facilitate program implementation.

Using Department of Veterans Affairs Software. Patient safety initiatives within DoD and the VA could result in concurrent development of multiple patient safety reporting programs, centers, and databases. The VA has already developed software for creating and maintaining a patient safety database. To keep program development cost at a minimum and facilitate the sharing and consolidation of patient safety data, we believe DoD should use the VA patient safety database software.

Congress encourages DoD and the VA to share, when possible, health care facilities and staff. Senior managers with the VA patient safety reporting program would prefer not to maintain a joint database because DoD is only in the early stages of implementing the program, but the VA did offer to share the database software with DoD. However, during the pilot program, OASD(HA) plans to use an internally developed spreadsheet to collect data. We believe the VA software would enable DoD to avoid software development costs and facilitate future sharing between the VA and DoD of the patient safety data and lessons learned. In addition, it would be a major step toward ensuring that the

DoD patient safety information can be consolidated into a Federal patient safety reporting program which has been considered by the Congress and the President.

Conclusion

The Working Group has done a commendable job initiating a patient safety reporting program throughout DoD. The success so far is attributable in part to highly capable and motivated senior management and the decision to adopt the patient safety reporting program developed by the VA. The most challenging part of the program—training and implementation—is about to start. To date, much of the coordination and planning for the program has been based on verbal plans and commitments. However, no document exists that provides an overview of the program or links key areas such as goals and performance measures, workload management, staffing, training, and program software. In addition, military personnel who fill many of the key program management positions are subject to rotate to other positions. Therefore, development of a program strategy to ensure continuation of program direction and momentum is essential toward maximizing the potential for reducing medical errors as well as improving health care.

Recommendations, Management Comments, and Audit Response

Revised Recommendation. As a result of management comments, we revised Recommendation 5. to omit the requirement to use the Department of Veterans Affairs patient safety database software during the program pilot phase.

We recommend that the Assistant Secretary of Defense (Health Affairs) develop an implementation strategy for the proposed patient safety reporting program that at a minimum:

1. Identifies program goals and performance measures.

Management Comments. The Acting Assistant Secretary of Defense (Health Affairs) concurred and, in conjunction with the DoD Patient Safety Working Group, will develop a strategy that includes specific goals and performance measures.

2. Outlines a phased approach for reporting adverse events.

Management Comments. The Acting Assistant Secretary of Defense (Health Affairs) concurred but provided alternative procedures to minimize the administrative burden on the facilities and the Armed Forces Institute of Pathology. Pilot test results of a new reporting format for close calls and low severity adverse events indicate that data management can be streamlined.

Also, including quarterly aggregated reviews for adverse drug events and falls in the DoD Patient Safety Program will provide necessary data while reducing reporting requirements.

Audit Response. The comments are fully responsive. Planned action to include the revised reporting format and quarterly aggregated reviews meets the intent of the recommendation to reduce the burden of data management during program implementation. In addition, the actions should reduce the burden throughout the life of the program.

3. Includes the full-time core staffing required to establish and maintain the program.

Management Comments. The Acting Assistant Secretary of Defense (Health Affairs) concurred and is requesting a management analysis by the Army as the executive agent for the Armed Forces Institute of Pathology to determine the staffing needs for the Patient Safety Center.

4. Requires Military Treatment Facilities to send patient safety personnel to program training prior to participating in the patient safety reporting program.

Management Comments. The Acting Assistant Secretary of Defense (Health Affairs) concurred and revised the draft DoD instruction on the Patient Safety Program. The instruction is expected to be issued in January 2001.

5. Requires the use of the Department of Veterans Affairs software for creating and maintaining a patient safety database.

Management Comments. The Acting Assistant Secretary of Defense (Health Affairs) concurred, stating that the Department of Veterans Affairs software is in the final stages of development. Minor software modifications are necessary because of differences in patient populations and health care systems, and the software is expected to be used in the next phase of the program beginning in the spring 2001.

Audit Response. The comments are fully responsive. The recommendation in the draft report included the requirement to use the software during the program pilot phase. As stated in the management comments, the software will not be available for use until the next phase of the program begins in the spring 2001. Therefore, the recommendation was revised to omit the requirement to use the software during the pilot phase.

Appendix A. Audit Process

Scope and Methodology

Work Performed. The audit reviewed collecting and reporting of quality assurance data within the MHS. We interviewed OASD(HA) personnel responsible for developing the proposed DoD patient safety reporting program. We reviewed the draft DoD patient safety instruction that was distributed among DoD Components in April 2000 for coordination. We reviewed the IOM report that estimated the number of patients that may die each year in the United States as a result of medical errors. We did not evaluate the validity of the estimate. We also reviewed the QuIC report that considered the recommendations in the IOM report and reported to the President that DoD would implement a patient safety reporting program.

The proposed DoD patient safety reporting program is modeled after a patient safety reporting program developed by the VA. We interviewed personnel responsible for managing the patient safety effort at the VA National Center for Patient Safety. We also reviewed the methodology the VA is using to implement and manage the patient safety reporting program.

The draft DoD patient safety instruction assigns the AFIP responsibility for managing and maintaining a database for patient safety information. We interviewed personnel with the Department of Legal Medicine at the AFIP who will be responsible for managing and maintaining the database. We reviewed AFIP plans to manage, staff, and fund the database effort.

We interviewed management representatives from the Army Medical Command, Naval Bureau of Medicine and Surgery, and the Office of the Air Force Surgeon General who are responsible for the patient safety effort within the Military Departments. We reviewed the guidance issued between December 1989 and August 2000 by each Military Department that requires MTFs to establish programs to monitor and improve patient safety. We visited six MTFs (one medical center and one community hospital from each Military Department) and reviewed procedures for collecting and reporting patient safety information. We also reviewed MTF patient safety documentation dated from November 1998 through May 2000. Specifically, we reviewed adverse event reports, sentinel event reports, peer review documentation, and minutes from committees at the MTFs that were established to monitor patient safety efforts. We did not question judgments on whether adverse events were reportable sentinel events.

DoD-Wide Corporate Level Coverage. In response to the Government Performance and Results Act, the Secretary of Defense annually establishes DoD-wide corporate level goals, subordinate performance goals, and performance measures. This report pertains to achievement of the following goal and subordinate performance goals:

> **FY 2001 DoD Corporate Level Goal 2:** Prepare now for an uncertain future by pursuing a focused modernization effort that maintains U.S. qualitative superiority in key warfighting capabilities. Transform the force by exploiting the Revolution in Military Affairs, and reengineer the Department to achieve a 21st century infrastructure. **(01-DoD-2) FY 2001**
>
> **Subordinate Performance Goal 2.3:** Streamline the DoD infrastructure by redesigning the Department's support structure and pursuing business practice reforms. **(01-DoD-2.3).**

DoD Functional Area Reform Goals. Most major DoD functional areas have also established performance improvement reform objectives and goals. This report pertains to achievement of the following functional area objectives and goals.

- **Health Care. Objective:** Become a benchmark health system. **Goal:** Measure health outcomes and customer satisfaction to identify opportunities for improvement.

High-Risk Area. The General Accounting Office has identified several high-risk areas in DoD. This report provides coverage of the Defense Infrastructure and Information Management and Technology high-risk areas.

Use of Computer-Processed Data. We did not use computer-processed data to perform this audit.

Audit Type, Dates, and Standards. This program audit was performed from April through August 2000 in accordance with auditing standards issued by the Comptroller General of the United States, as implemented by the Inspector General, DoD.

Contacts During the Audit. We visited or contacted individuals and organizations within and outside of DoD. Further details are available on request.

Prior Coverage

During the last 5 years, the General Accounting Office and the Inspector General, DoD, issued two reports discussing patient safety and medical errors. Unrestricted General Accounting Office reports can be accessed over the Internet at http://www.gao.gov. Unrestricted Inspector General, DoD, reports can be accessed at http://www.dodig.osd.mil/audit/reports.

General Accounting Office

General Accounting Office Report No. HEHS-00-21, "Adverse Drug Events: The Magnitude of Health Risk is Uncertain Because of Limited Incidence Data," January 18, 2000

Inspector General, DoD

Inspector General, DoD, Report No. 98-168, "DoD Implementation of the National Practitioner Data Bank Guidelines," June 26, 1998

Appendix B. Report Distribution

Office of the Secretary of Defense

Under Secretary of Defense (Comptroller)
    Deputy Chief Financial Officer
    Deputy Comptroller (Program/Budget)
Assistant Secretary of Defense (Health Affairs)

Department of the Army

Auditor General, Department of the Army

Department of the Navy

Naval Inspector General
Auditor General, Department of the Navy

Department of the Air Force

Assistant Secretary of the Air Force (Financial Management and Comptroller)
Auditor General, Department of the Air Force

Non-Defense Federal Organizations

Office of Management and Budget

Congressional Committees and Subcommittees, Chairman and Ranking Minority Member

Senate Committee on Appropriations
Senate Subcommittee on Defense, Committee on Appropriations
Senate Committee on Armed Services
Senate Committee on Governmental Affairs
House Committee on Appropriations
House Subcommittee on Defense, Committee on Appropriations
House Committee on Armed Services
House Committee on Government Reform
House Subcommittee on Government Management, Information, and Technology, Committee on Government Reform
House Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform

Assistant Secretary of Defense (Health Affairs) Comments

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

DEC 14 2000

Donald Mancuso
Acting Inspector General
Department of Defense
400 Army Navy Drive
Arlington, VA 22202-2885

Dear Mr. Mancuso:

I appreciate the fine work you and your staff have done in preparing the Audit Report on Collection and Reporting of Patient Safety Data Within the Military Health System (Project No. D2000LF-0195). I concur with the report's findings and most of the five recommendations:

1. Identifies program goals and reporting measures.

I concur with this recommendation. An implementation strategy for the patient safety reporting program including clear goals and reporting measures is essential. We are working closely with the DoD Patient Safety Working Group to develop a strategy that includes the recommendations made in your draft report and steps to meet the new requirements of the FY 2001 Defense Authorization Act.

2. Outlines a phased approach for reporting adverse events.

I share your concerns about the size of the data management task that faces AFIP when the reporting system is instituted. Two recent developments, however, lead me to a strategy other than the phased approach you recommend. One is the pilot testing of a reporting system for close calls and low severity adverse events developed by the Air Force Material Command. Eleven MTFs in the AFMC have been participating in the pilot. They use a streamlined reporting format for tracking and trending close calls and low severity adverse events. The response to the process by the AFMC facilities has been very positive and the data management burden has been minimal. The report form has been modified slightly and is being used in the pilot phase of the DoD Patient Safety Program. The second is the development of the quarterly aggregated review tool. This tool was developed by the Department of Veterans Affairs for the reporting and analysis of their most common types of close calls and low severity adverse events. It is being used in the DoD Patient Safety Program pilot for adverse drug events and falls. This approach should give us essential information while minimizing the burden on the facilities and the AFIP.

3. Includes the full-time core staffing required to establish and maintain the program.

I concur with this recommendation. I am requesting a management analysis by the Army as the executive agent for the Armed Forces Institute of Pathology to determine the staffing needs for the Patient Safety Center.

4. Requires Military Treatment Facilities to send patient safety personnel to program training prior to participating in the patient safety reporting program.

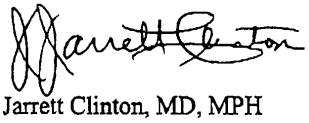
I concur with this recommendation. That has been the intention throughout the development of the program. The draft DoD instruction has been revised to make that requirement explicit. It will be issued by January 2001.

5. Requires the use of the Department of Veterans Affairs software for creating and maintaining a patient safety database, beginning with the pilot phase.

I agree that use of the VA software for the patient safety database could save money and facilitate the sharing and consolidation of patient safety data. The software VA is currently using is a temporary solution. Their new database software is in the final stages of development and is expected to be ready for testing this fall. AFIP has developed a set of Access databases to manage the data from the pilot program. The VA software will require some minor modifications for use in DoD because of the difference in the patient populations and in the structures of the healthcare systems. I hope that the software will be ready for use in the next phase of the program beginning in Spring 2001.

My point of contact for this issue is CAPT Frances Stewart, MC, USN. CAPT Stewart can be reached via telephone at (703) 681-1703, ext. 5214, fax (703)681-3658 or email: frances.stewart@ha.osd.mil.

Sincerely,



J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

Audit Team Members

The Readiness and Logistics Support Directorate, Office of the Assistant Inspector General for Auditing, DoD, prepared this report. Personnel of the Office of the Inspector General, DoD, who contributed to the report are listed below.

Shelton R Young
Raymond D. Kidd
Michael A. Joseph
Sanford W. Tomlin
G. Paul Johnson
James A. O'Connell
James K. Knight
Eva M. Zahn